IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

NOVO NORDISK A/S AND NOVO NORDISK INC., Plaintiffs, v. ADVANCED VITOLOGY HRT, LLC, Defendant.	Case No. 2:24-cv-4057

COMPLAINT

Plaintiffs Novo Nordisk A/S ("NNAS") and Novo Nordisk Inc. ("NNI") (collectively, "Plaintiffs" or "Novo Nordisk") file their complaint against Advanced Vitology HRT, LLC, which does business under the trade name Advanced Vitality HRT ("Defendant"), for trademark infringement and false advertising and seek injunctive, monetary, and other relief. Plaintiffs allege as follows, on actual knowledge with respect to themselves and their own acts and on information and belief as to all other matters.

INTRODUCTION

1. Novo Nordisk is a healthcare company with a 100-year history of innovation in developing medicines to treat serious chronic diseases like diabetes and obesity.

2. The development of semaglutide is an example of Novo Nordisk's commitment to innovation for those living with chronic diseases. Semaglutide is the foundational molecule that serves as the primary ingredient for Novo Nordisk's three prescription-only medicines approved by the Food and Drug Administration ("FDA"): Ozempic® (semaglutide) injection and Rybelsus® (semaglutide) tablets for adults with type 2 diabetes and Wegovy® (semaglutide) injection for chronic weight management.

3. Novo Nordisk is the only company in the United States with FDA-approved medicines containing semaglutide and is the only company authorized to identify its FDA-approved semaglutide medicines using the trademarks Ozempic®, Wegovy®, and Rybelsus®.

4. The FDA has not approved any generic versions of semaglutide. To the contrary, the FDA has sent warning letters to companies which claimed that their unapproved drug products have the "same active ingredient as Ozempic, Rybelsus, and Wegovy," noting that the Ozempic® and Wegovy® medicines are currently the only "two injectable semaglutide products FDA-approved for the U.S. market."[1]

5. Plaintiffs bring this action pursuant to the Lanham Act, 15 U.S.C. §§ 1051 *et seq*., related state laws, and the common law arising out of Defendant's infringement of Plaintiffs' rights in their Ozempic® and Wegovy® marks and Defendant's acts of false advertising and unfair competition.

6. Defendant uses, markets, and sells to patients compounded drug products that purport to contain semaglutide. Even though such compounded drug products have not been evaluated by the FDA for their safety, effectiveness, or quality, Defendant falsely and misleadingly represents to patients that its products are the same as, or equivalent to, Novo Nordisk's FDA-approved medicines.

7. Defendant's conduct is likely to confuse and deceive patients into mistakenly believing that they are purchasing authentic Novo Nordisk medicines or medicines that have been evaluated by the FDA, studied in clinical trials, and deemed safe and effective.

[1] FDA – Warning Letter to Ozempen.com, MARCS-CMS 684435 — JUNE 24, 2024, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ozempencom-684435-06242024#:~:text=WARNING%20LETTER&text=As%20discussed%20below%2C%20FDA%20has,new%20drugs%20and%20misbranded%20drugs.

THE PARTIES

8. Plaintiff NNAS is a corporation organized and existing under the laws of the Kingdom of Denmark and has its principal place of business in Bagsværd, Denmark.

9. Plaintiff NNI is a corporation organized and existing under the laws of Delaware and has its principal place of business in Plainsboro, New Jersey.

10. NNI promotes, offers, and sells Novo Nordisk's Ozempic® and Wegovy® medicines throughout the United States, including in this District. NNAS has granted to NNI exclusive rights to market, advertise, promote, offer for sale and sell Ozempic® and Wegovy® medicines in the United States.

11. Defendant Advanced Vitology HRT, LLC (trade name Advanced Vitality HRT) is an Ohio limited liability company with a registered business address at 3805 Edwards Rd #100, Cincinnati, Ohio 45209 in this judicial district.

12. Defendant sells and promotes compounded drug products that purport to contain semaglutide and that are not approved by the FDA ("Unapproved Compounded Drugs") and makes false and misleading statements to sell and promote Unapproved Compounded Drugs masquerading as the Ozempic® and Wegovy® medicines.

JURISDICTION AND VENUE

13. The Court has subject matter jurisdiction over the Lanham Act causes of action pleaded herein pursuant to 35 U.S.C. § 1121 and 28 U.S.C. § 1338(a). The Court has supplemental jurisdiction over the state and common law causes of action pleaded herein pursuant to 28 U.S.C. § 1338(b).

14. Defendant is subject to personal jurisdiction in this Court because Defendant is registered in the State of Ohio and has a principal place of business in this District.

15. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendant operates in this District, manufactures and sells its compounded drug products that purport to contain semaglutide in this District, and otherwise conducts business in this District.

NOVO NORDISK'S FDA-APPROVED SEMAGLUTIDE MEDICINES AND OZEMPIC® AND WEGOVY® TRADEMARKS

16. Plaintiffs use the trademarks "Ozempic" and "Wegovy" to identify and promote the FDA-approved Ozempic® and Wegovy® medicines. The Ozempic® and Wegovy® medicines are sold and marketed in the United States by NNAS's indirect, wholly-owned subsidiary, NNI.

17. The Ozempic® medicine is indicated for adults with type 2 diabetes to improve blood sugar (glucose), along with diet and exercise.

18. The Ozempic® medicine also lowers the risk of major cardiovascular events such as stroke, heart attack, or death in adults with type 2 diabetes and known heart disease.

19. The Wegovy® medicine is indicated to reduce excess body weight and maintain weight reduction long term in adults and children aged ≥ 12 years with obesity, and some adults with overweight and weight-related medical problems, along with a reduced calorie diet and increased physical activity.

20. The Wegovy® medicine is also indicated, with a reduced calorie diet and increased physical activity, to reduce the risk of major adverse cardiovascular events such as "cardiovascular" death, heart attack, or stroke in adults with known heart disease and with either obesity or overweight.

21. The Ozempic® and Wegovy® medicines have been extensively studied in clinical trials and are FDA-approved.

22. Each of the Ozempic® and Wegovy® medicines has a unique safety and efficacy profile which is detailed in its respective product label.

23. The Ozempic® and Wegovy® medicines are prescription-only medicines that should only be prescribed in direct consultation with, and under the supervision of, a licensed healthcare professional.

24. Novo Nordisk first adopted and used the Ozempic® mark at least as early as 2017, and has used it continuously since that time.

25. The Ozempic® trademark is inherently distinctive.

26. Novo Nordisk has promoted, advertised, and marketed its prescription-only medicine using the Ozempic® mark in many different channels, directed to physicians, other health care professionals, and patients, including on the websites ozempic.com and novonordisk-us.com. As a result of its use of the Ozempic® mark, NNAS owns valuable common law rights in and to the Ozempic® mark.

27. Plaintiff NNAS is the owner of U.S. trademark registration number 4,774,881, issued on July 21, 2015, for the mark Ozempic® for pharmaceutical preparations, in International Class 5. A true and correct copy of Plaintiff NNAS's registration for the Ozempic® mark is attached hereto as **Exhibit A**.

28. Novo Nordisk's right to use its registered Ozempic® mark is incontestable.

29. Novo Nordisk first adopted and used the Wegovy® mark at least as early as 2021, and has used it continuously since that time.

30. The Wegovy® trademark is inherently distinctive.

31. Novo Nordisk has promoted, advertised, and marketed its prescription-only medicine using the Wegovy® mark in many different channels, directed to physicians, other health care professionals, and patients, including on the websites wegovy.com and novonordisk-us.com. As a result of its use of the Wegovy® mark, NNAS owns valuable common law rights in and to the Wegovy® mark.

32. Plaintiff NNAS is the owner of (a) U.S. trademark registration number 6,585,492, issued on December 14, 2021, for the mark Wegovy® for pharmaceutical preparations, in International Class 5; and (b) U.S. trademark registration number 6,763,029, issued on June 21, 2022, for the mark Wegovy® in a stylized form for pharmaceutical preparations, in International Class 5. True and correct copies of Plaintiff's registrations numbers 6,585,492 and 6,763,029 for the Wegovy® mark are attached hereto as **Exhibit B** and **Exhibit C**, respectively.

33. As a result of Novo Nordisk's long use, promotion, and advertising of the Ozempic®, Wegovy®, and Rybelsus® trademarks and medicines, the Ozempic®, Wegovy®, and Rybelsus® marks are exclusively associated with Plaintiffs, serve to identify genuine Novo Nordisk medicines, and are valuable assets of Novo Nordisk.

34. As a result of Novo Nordisk's long use, promotion, and advertising of the Ozempic® and Wegovy® trademarks and medicines, the Ozempic® and Wegovy®, and trademarks are well-known, strong, and famous marks, and became such prior to any of the acts of Defendant complained of herein.

DEFENDANT'S SALE OF UNAPPROVED COMPOUNDED DRUGS

35. Novo Nordisk has not authorized Defendant to use its marks, has not provided Defendant with Novo Nordisk's FDA-approved semaglutide medicines, and does not sell the bulk semaglutide in Novo Nordisk's FDA-approved semaglutide medicines to any compounding pharmacies from which it may be sourcing its Unapproved Compounded Drugs.

36. Defendant markets and sells to patients Unapproved Compounded Drugs that purport to contain semaglutide.

37. The FDA has not approved the Unapproved Compounded Drugs.

38. On information and belief, the Unapproved Compounded Drugs sold by Defendant are made by compounding pharmacies, which deliver them either directly to patients or to Defendant for administration or dispensing to patients.

39. The FDA defines compounding as a "practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient."[2]

40. According to the FDA, "[c]ompounded drugs are not FDA-approved. This means that FDA does not review these drugs to evaluate their safety, effectiveness, or quality before they reach patients."[3]

41. The FDA has further stated that compounded drugs "do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of compounded drugs unnecessarily exposes patients to potentially serious health risks."[4] As the FDA has explained, "[c]ompounded drugs pose a higher risk to patients than FDA-approved drugs because compounded drugs do not undergo FDA premarket review for safety, quality or effectiveness. Compounded drugs should only be used for patients whose medical needs cannot be met by an available FDA-approved drug."[5]

42. Based on data as of June 30, 2024, the FDA's Adverse Event Reporting System (FAERS) database includes 542 cases of adverse events associated with compounded "semaglutide."[6] Of those cases, 388 were classified as "serious" adverse events, 124 reported

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[2] Human Drug Compounding, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding.
[3] Compounding Laws and Policies, https://www.fda.gov/drugs/human-drug-compounding/compounding-laws-and-policies.
[4] Compounding and the FDA: Questions and Answers, https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers.
[5] FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products, https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded.
[6] FDA Adverse Event Reporting System (FAERS) Public Dashboard, https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard (last visited July 31, 2024).

hospitalization, and ten involved deaths, more than twice the number of adverse events for all compounded drugs in 2022.

43. The FDA has received reports of adverse events, some requiring hospitalization, related to overdoses from dosing errors associated with compounded "semaglutide" products.[7] In several instances, patients mistakenly administered five to 20 times more than the intended dose of compounded "semaglutide."

44. The FDA has stated that the containers and packaging used by compounders, including multidose vials and prefilled syringes, the varying product concentrations, and the instructions accompanying the compounded drug contribute to the potential medical errors.[8]

45. A previous publication from the Journal of the American Pharmacists Association also highlighted administration errors where patients accidentally self-administered doses of compounded "semaglutide" up to 10 times greater than the intended amount.[9]

46. FDA has issued guidance on "Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss," which provides that: (1) "compounded drugs are not FDA-approved or evaluated for safety and effectiveness"; and (2) "FDA has received adverse event reports after patients used compounded semaglutide. Patients should not use a compounded drug if an approved drug is available to treat a patient. Patients and health care professionals should understand that the agency does not review compounded versions of these drugs for safety, effectiveness, or quality."

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[7] FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products, https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded.

[8] *Id.*

[9] Joseph E. Lambson et al, *Administration Errors of Compounded Semaglutide Reported to a Poison Control Center—Case Series*, 63 J. Am. Pharmacists Assc'n 5 (2023), available at https://www.japha.org/article/S1544-3191(23)00231-5/abstract.

DEFENDANT'S TRADEMARK INFRINGEMENT AND FALSE ADVERTISING IN CONNECTION WITH ITS SALE OF UNAPPROVED COMPOUNDED DRUGS

47. Despite the foregoing, and well after NNAS's first use and registration of its Ozempic® and Wegovy® marks, Defendant has used Novo Nordisk's Ozempic® and Wegovy® trademarks to market and sell Unapproved Compounded Drugs purporting to contain "semaglutide" that are neither Ozempic® nor Wegovy®, and has made false and misleading representations to patients regarding the nature of its Unapproved Compounded Drugs.

48. Defendant has, for example, used Novo Nordisk's Ozempic® and Wegovy® trademarks to identify and market its Unapproved Compounded Drugs.

49. Defendant unlawfully advertises its Unapproved Compounded Drugs by making statements that describe Ozempic® and Wegovy® but that are false or misleading when in reference to Defendant's Unapproved Compounded Drugs.

50. Defendant has claimed or implied that its Unapproved Compounded Drugs have been approved by the FDA or have been reviewed by the FDA for safety, effectiveness, and quality.

51. Defendant has claimed or implied that its Unapproved Compounded Drugs contain the same semaglutide that the FDA evaluated in the context of reviewing and approving Novo Nordisk's new drug applications for the Ozempic® and Wegovy® medicines.

52. Defendant has claimed or implied that its Unapproved Compounded Drugs are generic versions of the Wegovy® and Ozempic® medicines.

53. The claims in the preceding three paragraphs are false and misleading.

54. On information and belief, Defendant has engaged and continues to engage in these unlawful practices to attract customers and generate revenues and profits, including by passing off its Unapproved Compounded Drugs purporting to contain "semaglutide" as the Ozempic® and Wegovy® medicines or authorized variations of those medicines.

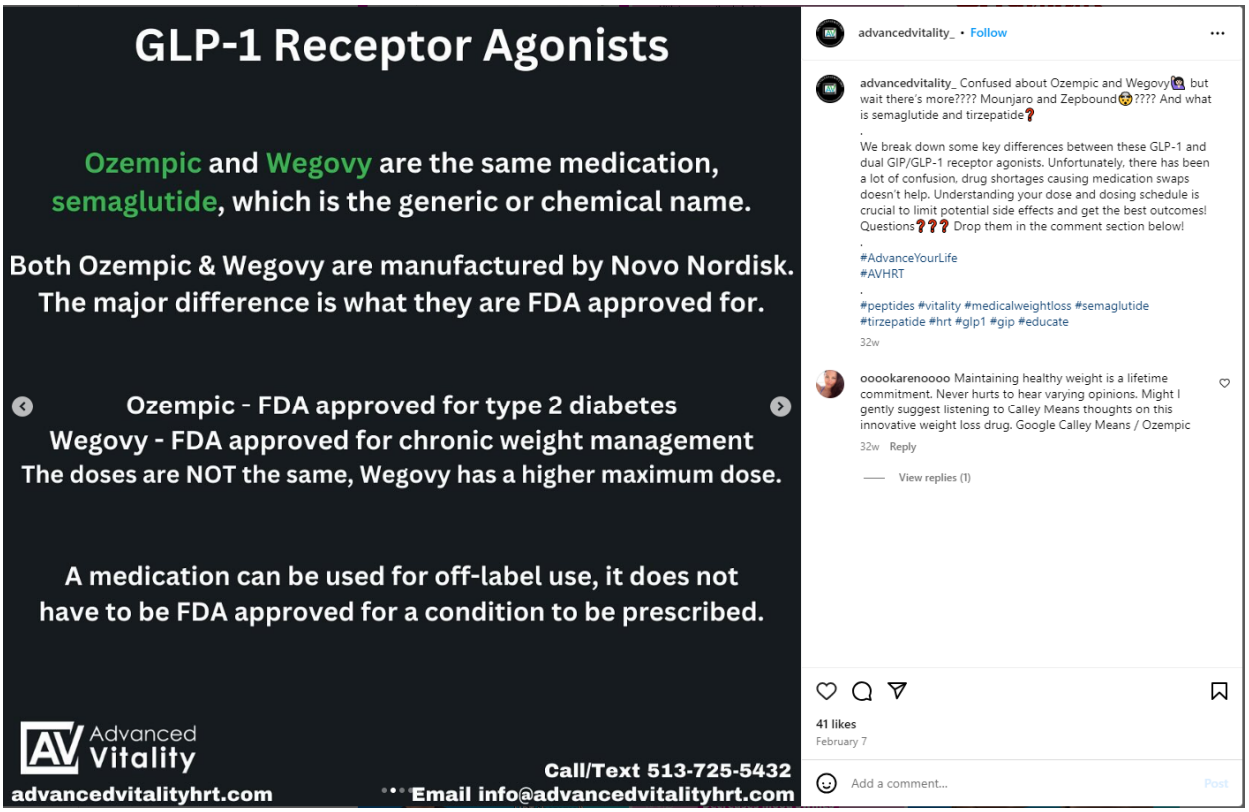
55. Defendant's prominent and misleading use of the Ozempic® and Wegovy® marks is likely to cause patients to believe falsely that they are actually purchasing genuine Ozempic® and Wegovy® medicines; that Defendant is a source for Novo Nordisk's FDA-approved semaglutide medicines; and/or that Defendant's services are provided, licensed, sponsored, authorized, or approved by Novo Nordisk.

56. Defendant's use of the Ozempic® and Wegovy® marks is without the permission, consent or authorization of Novo Nordisk. Defendant has no right to use, and Defendant knows that it has no right to use, the Ozempic® and Wegovy® marks in connection with Defendant's Unapproved Compounded Drugs or otherwise.

57. Novo Nordisk has no control over the nature, quality, or efficacy of the products sold by Defendant, including the Unapproved Compounded Drugs.

58. Illustrative examples of Defendant's false advertising are collected in the paragraphs that follow, as well as **Exhibit D** hereto.

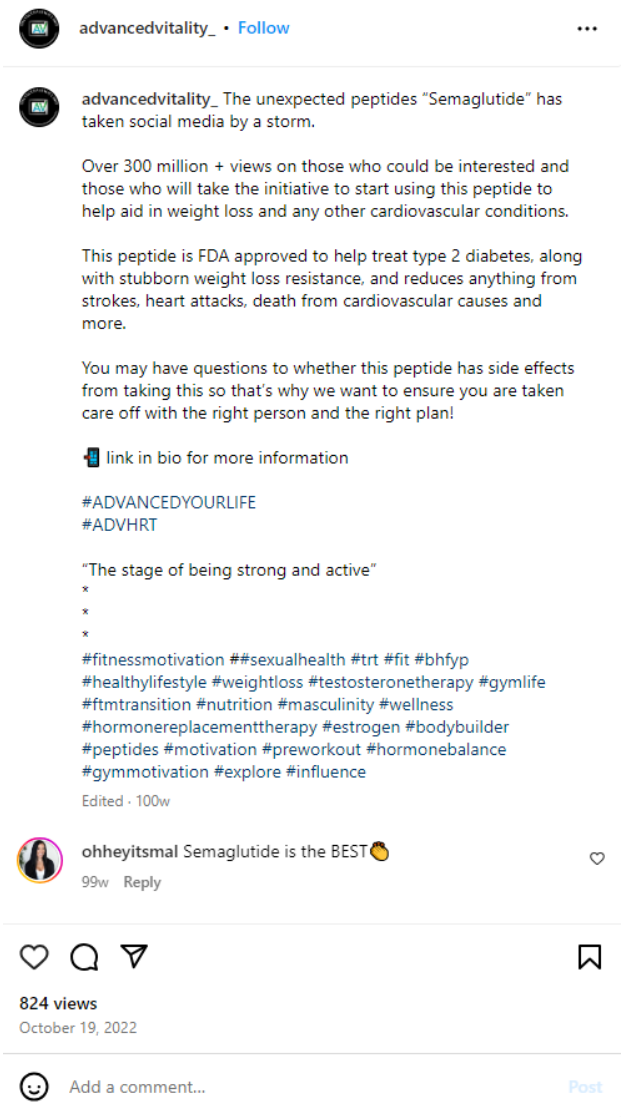
59. Defendant erroneously advertises to its customers that the semaglutide in its Unapproved Compounded Drugs is the "generic or chemical name" for the Ozempic® and Wegovy® medicines and states that the Ozempic® and Wegovy® medicines are "brand names" of its Unapproved Compounded Drugs:



60. Such statements falsely indicate that Defendant's Unapproved Compounded Drugs are the same as, or a generic version of, the Ozempic® or Wegovy® medicines.

61. Defendant's Unapproved Compounded Drugs are not a "generic" of Novo Nordisk's medicines. A generic drug is one that the FDA has found to meet the "same high standards of quality and manufacturing as the brand-name product."[10] No generic forms of Plaintiffs' FDA-approved Ozempic® and Wegovy® medicines exist.

62. As depicted below, Defendant has claimed or implied that its Unapproved Compounded Drugs have been approved by the FDA or have been reviewed by the FDA for safety, effectiveness, and quality:

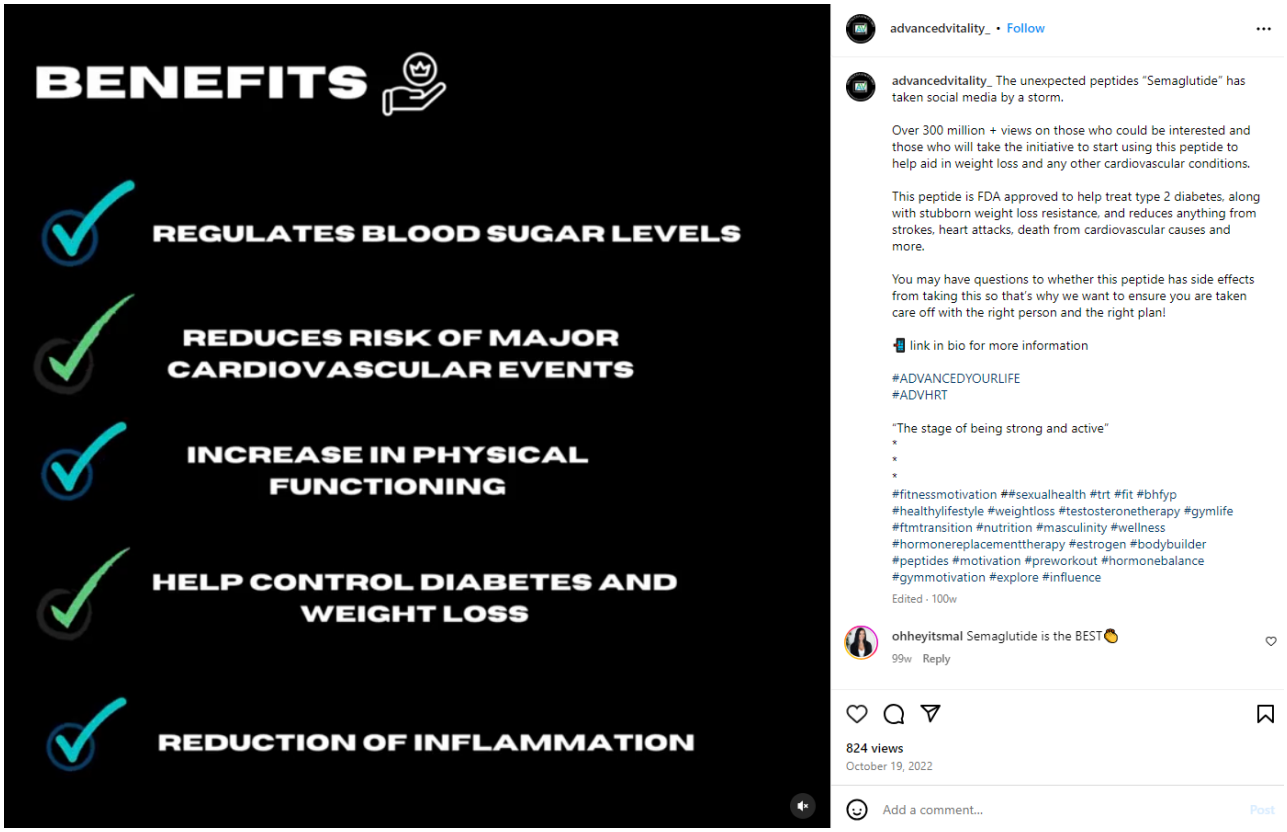


[10] U.S. Food & Drug Administration – Generic Drugs: Questions & Answers (March 16, 2021) https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers#:~:text=A%20generic%20drug%20is%20a,performance%20characteristics%2C%20and%20intended%20use.

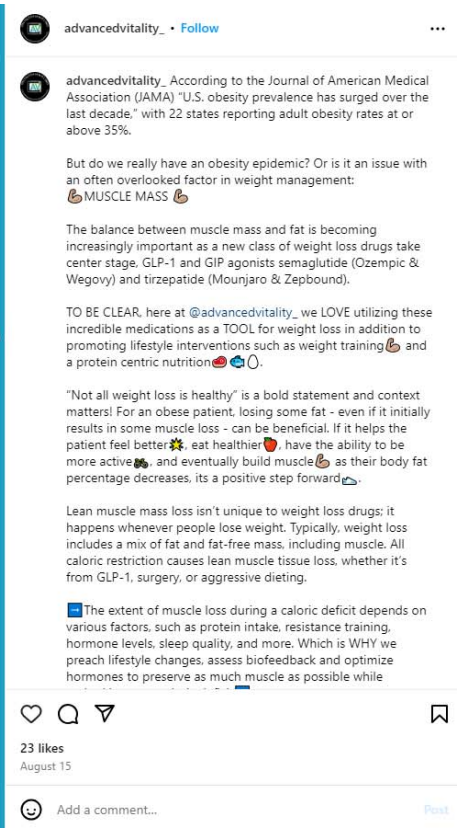
63. Such claims are false. The FDA has not reviewed or approved Defendant's Unapproved Compounded Drugs. Nor has the FDA reviewed or approved the putative "semaglutide" that those Unapproved Compounded Drugs might contain. To the contrary, the FDA approves complete drug products, like the Ozempic® or Wegovy® medicines.

64. Defendant has also falsely advertised its Unapproved Compounded Drugs by making statements that describe the Ozempic® or Wegovy® medicines but that are false or misleading when in reference to Defendant's Unapproved Compounded Drugs.

65. As depicted below, Defendant has claimed or implied that its Unapproved Compounded Drugs have been subjected to clinical studies and trials, or have otherwise achieved certain therapeutic outcomes attributable to the Wegovy® or Ozempic® medicines:




NOT ALL WEIGHT LOSS IS HEALTHY
Do you agree or disagree?
With the rise of popular weight loss medications such as semaglutide and tirzepatide, we are seeing incredible weight loss but at what cost?
A 2023 study in The Lancet confirms semaglutide's efficacy, showing that adults lose about 15 percent of their body weight on average with GLP-1 agonists.
A 2021 clinical trial in the New England Journal of Medicine highlights a concerning downside: With GLP-1 agonists (semaglutide), about 40 percent of the weight lost is lean mass, including muscle.
Advanced Vitality
info@advancedvitalityhrt.com
(513) 725-5432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advancedvitality_ According to the Journal of American Medical Association (JAMA) "U.S. obesity prevalence has surged over the last decade," with 22 states reporting adult obesity rates at or above 35%.
But do we really have an obesity epidemic? Or is it an issue with an often overlooked factor in weight management:
MUSCLE MASS
The balance between muscle mass and fat is becoming increasingly important as a new class of weight loss drugs take center stage, GLP-1 and GIP agonists semaglutide (Ozempic & Wegovy) and tirzepatide (Mounjaro & Zepbound).
TO BE CLEAR, here at @advancedvitality_ we LOVE utilizing these incredible medications as a TOOL for weight loss in addition to promoting lifestyle interventions such as weight training and a protein centric nutrition.
"Not all weight loss is healthy" is a bold statement and context matters! For an obese patient, losing some fat - even if it initially results in some muscle loss - can be beneficial. If it helps the patient feel better, eat healthier, have the ability to be more active, and eventually build muscle as their body fat percentage decreases, its a positive step forward.
Lean muscle mass loss isn't unique to weight loss drugs; it happens whenever people lose weight. Typically, weight loss includes a mix of fat and fat-free mass, including muscle. All caloric restriction causes lean muscle tissue loss, whether it's from GLP-1, surgery, or aggressive dieting.
The extent of muscle loss during a caloric deficit depends on various factors, such as protein intake, resistance training, hormone levels, sleep quality, and more. Which is WHY we preach lifestyle changes, assess biofeedback and optimize hormones to preserve as much muscle as possible while
23 likes
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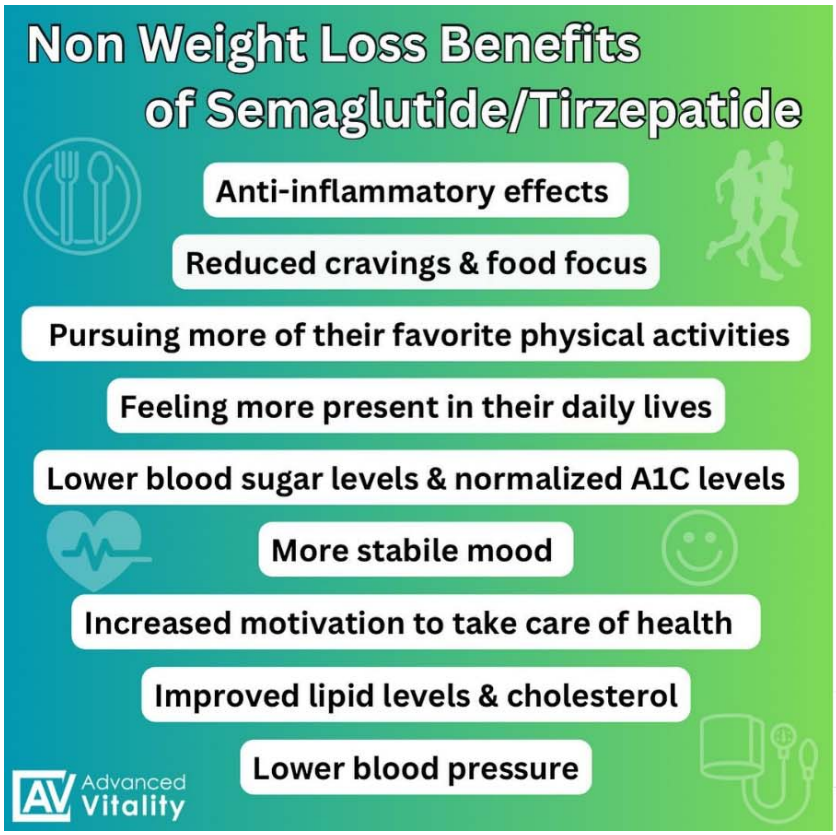
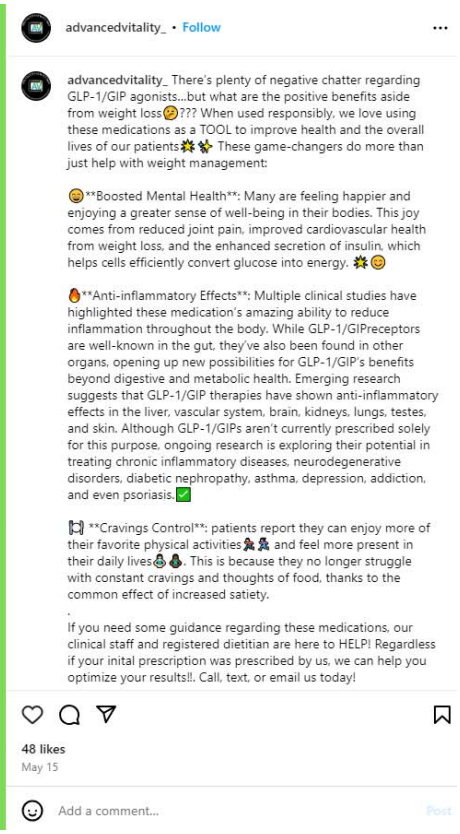
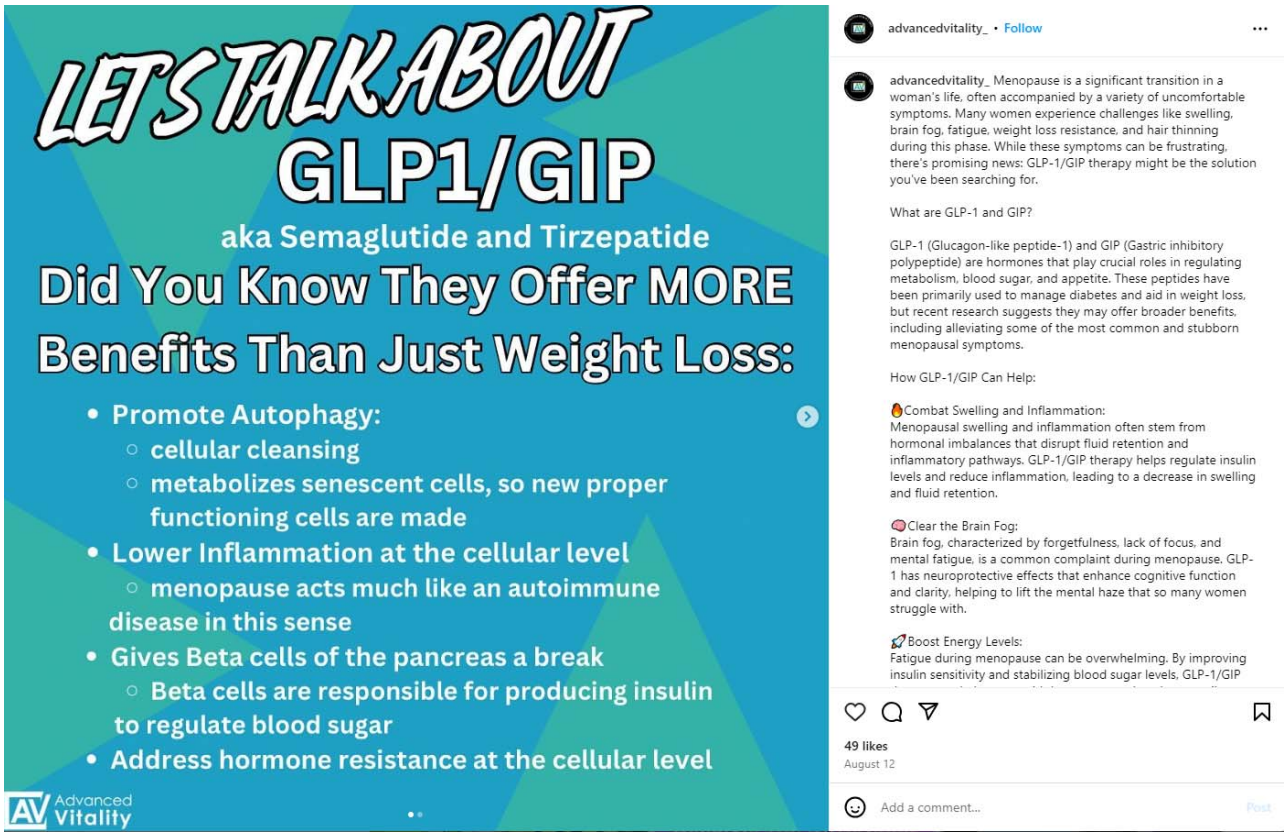

Non Weight Loss Benefits of Semaglutide/Tirzepatide
Anti-inflammatory effects
Reduced cravings & food focus
Pursuing more of their favorite physical activities
Feeling more present in their daily lives
Lower blood sugar levels & normalized A1C levels
More stabile mood
Increased motivation to take care of health
Improved lipid levels & cholesterol
Lower blood pressure
Advanced Vitality


advancedvitality_ • Follow
advancedvitality_ There's plenty of negative chatter regarding GLP-1/GIP agonists...but what are the positive benefits aside from weight loss??? When used responsibly, we love using these medications as a TOOL to improve health and the overall lives of our patients. These game-changers do more than just help with weight management:
Boosted Mental Health: Many are feeling happier and enjoying a greater sense of well-being in their bodies. This joy comes from reduced joint pain, improved cardiovascular health from weight loss, and the enhanced secretion of insulin, which helps cells efficiently convert glucose into energy.
Anti-inflammatory Effects: Multiple clinical studies have highlighted these medication's amazing ability to reduce inflammation throughout the body. While GLP-1/GIPreceptors are well-known in the gut, they've also been found in other organs, opening up new possibilities for GLP-1/GIP's benefits beyond digestive and metabolic health. Emerging research suggests that GLP-1/GIP therapies have shown anti-inflammatory effects in the liver, vascular system, brain, kidneys, lungs, testes, and skin. Although GLP-1/GIPs aren't currently prescribed solely for this purpose, ongoing research is exploring their potential in treating chronic inflammatory diseases, neurodegenerative disorders, diabetic nephropathy, asthma, depression, addiction, and even psoriasis.
Cravings Control: patients report they can enjoy more of their favorite physical activities and feel more present in their daily lives. This is because they no longer struggle with constant cravings and thoughts of food, thanks to the common effect of increased satiety.
If you need some guidance regarding these medications, our clinical staff and registered dietitian are here to HELP! Regardless if your inital prescription was prescribed by us, we can help you optimize your results!. Call, text, or email us today!
48 likes
May 15
Add a comment...



66. In reality, Novo Nordisk's FDA-approved medicines are the only drugs containing semaglutide to have undergone clinical trials for the indications above. On information and belief, no such data exist for Defendant's Unapproved Compounded Drugs.

67. Defendant's advertising and promotional materials are false and misleading, including by containing graphics of authentic Ozempic®-labeled products that suggest an association with Plaintiffs' FDA-approved Ozempic® and Wegovy® medicines when no such association exists:

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advancedvitality_ 🚨Exciting news🚨

Have you heard about popular weight loss medications like semaglutide (Ozempic/Wegovy) and tirzepatide (Mounjaro/Zepbound)? They're amazing tools when used right! 🌟

While there's no specific diet prescribed for success with these meds, don't worry! Our registered dietitian Alyssa is here to help you fine-tune your nutrition🍎. With her expert guidance, you'll be on track to achieve optimal results✅ while minimizing any potential side effects, ensuring the best possible outcomes. And remember, while it's not always the case, lifestyle tweaks often play a big role in long-term weight loss success🥱 Let's do this together! 💪.

Contact us today to work with Alyssa for YOUR best results!

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Our registered dietitian services are a standard monthly cost.

DM, Call/Text or Email to inquire

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☎️ 513-725-5432

📧 info@advancedvitalityhrt.com

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@alyssamcooke_scoobyhealth

#responsible #medicalweightloss #semaglutide #tirzepatide #weightloss #dietitian #hrt #registereddietitian #nutrition

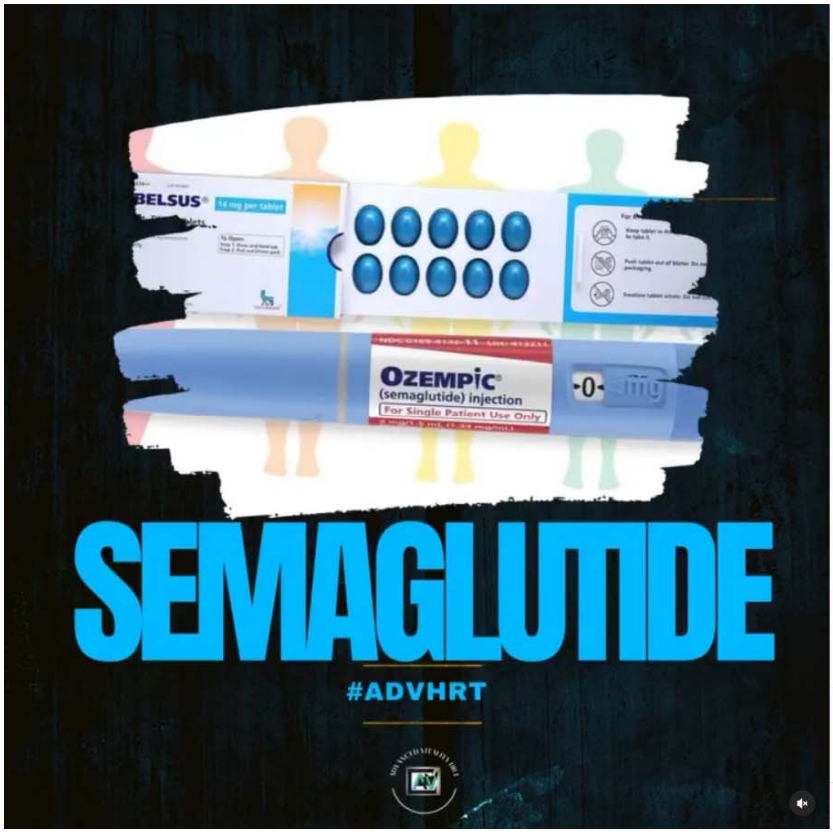
18w

alyssamcooke_scoobyhealth 🤓 here to help you optimize your health and nutrition ✅

18w 1 like Reply

20 likes

May 13



advancedvitality_ • Follow

advancedvitality_ The unexpected peptides "Semaglutide" has taken social media by a storm.

Over 300 million + views on those who could be interested and those who will take the initiative to start using this peptide to help aid in weight loss and any other cardiovascular conditions.

This peptide is FDA approved to help treat type 2 diabetes, along with stubborn weight loss resistance, and reduces anything from strokes, heart attacks, death from cardiovascular causes and more.

You may have questions to whether this peptide has side effects from taking this so that's why we want to ensure you are taken care off with the right person and the right plan!

📲 link in bio for more information

#ADVANCEDYOURLIFE
#ADVHRT

"The stage of being strong and active"
*
*
*
#fitnessmotivation ##sexualhealth #trt #fit #bhfyp #healthylifestyle #weightloss #testosteronetherapy #gymlife #ftmtransition #nutrition #masculinity #wellness #hormonereplacementtherapy #estrogen #bodybuilder #peptides #motivation #preworkout #hormonebalance #gymmotivation #explore #influence

Edited · 100w

ohheyitsmal Semaglutide is the BEST👏

99w Reply

824 views

October 19, 2022

Add a comment... Post

68. Defendant has used and continues to use the Ozempic® and Wegovy® marks without the permission, consent or authorization of Novo Nordisk to promote its Unapproved Compounded Drugs. Defendant has no right to use, and Defendant knows that it has no right to use, the Ozempic® and Wegovy® marks in connection with Defendant's Unapproved Compounded Drugs or otherwise.

69. Defendant's false and misleading statements and practices are likely to cause mistake and deception in the marketplace.

70. Defendant's false and misleading marketing is also likely to expose patients to unnecessary risks. Patients who mistakenly believe Defendant to be offering Novo Nordisk's FDA-approved medicines, or equivalent thereto, are unlikely to understand the unique risks associated with, or the lack of clinical trials or testing establishing the safety and effectiveness of, Defendant's Unapproved Compounded Drugs.[11]

71. On information and belief, unless enjoined by this Court, Defendant will continue to falsely advertise its products as being equivalent to, or associated with the Ozempic® and Wegovy® medicines, all in violation of Plaintiffs' rights.

FIRST CAUSE OF ACTION

Trademark Infringement in Violation of 15 U.S.C. § 1114(1)

72. Plaintiff NNAS realleges and incorporates each allegation in the preceding paragraphs of this Complaint as though fully set forth here.

73. Plaintiff NNAS's Ozempic® and Wegovy® marks are inherently distinctive, strong, valid, and protectable trademarks owned by Plaintiff NNAS.

[11] *See, e.g.*, Dozens Say They Lost Eyesight After Routine Surgery Using Compounded Pharmacy Drugs, WFAA, https://www.wfaa.com/article/news/do-not-publish-yet/287-5f002ed3-e110-4063-9959-a2e5f54b5097 (reporting mistaken belief of patient taking a compounded drug that "every pill you take, every shot you take is tested.").

74. Plaintiff NNAS's right to use its Ozempic® mark is incontestable and therefore constitutes conclusive evidence of the validity of the mark, of Plaintiff NNAS's registration and ownership of the mark, and of Plaintiff NNAS's exclusive right to use the mark in commerce on or in connection with the goods identified in the registration.

75. Plaintiff NNAS's trademark registrations for its Wegovy® marks constitute *prima facie* evidence of the validity of the marks, of Plaintiff NNAS's registration and ownership of the marks, and of Plaintiff NNAS's exclusive right to use the marks in commerce on or in connection with the goods identified in the registrations.

76. By virtue of its prior use and registration, Plaintiff NNAS has priority over Defendant with respect to the use of the Ozempic® and Wegovy® marks for pharmaceutical preparations sold in the United States.

77. Defendant uses the Ozempic® and Wegovy® marks in connection with the sale, advertising, and promotion of Unapproved Compounded Drugs purporting to contain semaglutide.

78. Defendant's use in commerce of the Ozempic® and Wegovy® marks is likely to cause confusion, to cause mistake, or to deceive with respect to Plaintiff NNAS's identical marks.

79. The above-described acts of Defendant constitute infringement of registered trademarks in violation of Section 32(1) of the Lanham Act, 15 U.S.C. § 1114(1), entitling Plaintiff NNAS to relief.

80. Defendant has unfairly profited from its trademark infringement.

81. By reason of Defendant's acts of trademark infringement, Plaintiff NNAS has suffered damage to the goodwill associated with its marks.

82. Defendant's acts of trademark infringement have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiff NNAS, its federally registered trademarks and the valuable goodwill associated with those trademarks.

83. Defendant's acts of trademark infringement have irreparably harmed, and if not enjoined, will continue to irreparably harm the interests of the public in being free from confusion, mistake, and deception.

84. By reason of Defendant's acts, Plaintiff NNAS's remedies at law are not adequate to compensate for the injuries inflicted by Defendant. Accordingly, Plaintiff NNAS is entitled to entry of preliminary and permanent injunctive relief pursuant to 15 U.S.C. § 1116.

85. By reason of Defendant's willful acts of trademark infringement, Plaintiff NNAS is entitled to disgorgement of Defendant's profits (enhanced at the Court's discretion), treble damages, and costs under 15 U.S.C. § 1117.

86. This case is exceptional, making Plaintiff NNAS eligible for an award of attorneys' fees under 15 U.S.C. § 1117.

SECOND CAUSE OF ACTION

Trademark Infringement, False Designation of Origin, and Unfair Competition in Violation of 15 U.S.C. § 1125(a)(1)(A)

87. Plaintiffs reallege and incorporate each allegation in the preceding paragraphs of this Complaint as though fully set forth here.

88. Defendant uses the Ozempic® and Wegovy® marks in commerce in connection with Defendant's goods and services and in commercial advertising and promotion of its goods and services.

89. Defendant uses the Ozempic® and Wegovy® marks in commerce in a manner that is likely to cause confusion, or to cause mistake, or to deceive the relevant public into believing that Defendant's goods or services are authorized, sponsored, approved by, or otherwise affiliated with Plaintiffs, with Plaintiffs' genuine Ozempic® and Wegovy® medicines, and with the Ozempic® and Wegovy® marks.

90. The above-described acts of Defendant constitute infringement of the Ozempic® and Wegovy® marks and use of false designations of origin in violation of Section 43(a)(1)(A) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(A), entitling Plaintiffs to relief.

91. Defendant has unfairly profited from the actions alleged.

92. By reason of the above-described acts of Defendant, Plaintiffs have suffered damage to the goodwill associated with the Ozempic® and Wegovy® trademarks.

93. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs, the Ozempic® and Wegovy® trademarks, and the valuable goodwill associated with the trademarks.

94. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

95. Because Plaintiffs' remedies at law are not adequate to compensate for all the injuries inflicted by Defendant, Plaintiffs are entitled to entry of preliminary and permanent injunctive relief pursuant to 15 U.S.C. § 1116.

96. Because the above-described acts of Defendant are willful, Plaintiffs are entitled to disgorgement of Defendant's profits (enhanced at the Court's discretion), treble damages, and costs under 15 U.S.C. § 1117.

97. This case is exceptional, making Plaintiffs eligible for an award of attorneys' fees under 15 U.S.C. § 1117.

THIRD CAUSE OF ACTION

Defendant's False and Misleading Advertising and Promotion in Violation of 15 U.S.C. § 1125(a)(1)(B)

98. Plaintiffs reallege and incorporate each allegation in the preceding paragraphs of this Complaint as though fully set forth here.

99. Defendant's practices, as described in this Complaint, constitute unfair competition and false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

100. Defendant has violated the Lanham Act by using false or misleading descriptions of fact and false or misleading representations of fact in its commercial advertising or promotion that misrepresent the nature, characteristics, and qualities of Defendant's business practices and products, as set forth above.

101. Defendant has also engaged in other false or misleading advertising and promotion intended to assure patients that Defendant's practices are lawful. On information and belief, Defendant provides patients who purchase Defendant's Unapproved Compounded Drugs (or who Defendant is trying to persuade to purchase its drugs) information that makes false or misleading statements, including those described herein and in the exhibits hereto.

102. The above-described acts of Defendant, if not enjoined by this Court, are likely to deceive members of the general public.

103. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs.

104. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

105. By reason of Defendant's acts as alleged above, Plaintiffs have suffered and will continue to suffer injuries, including injury to Plaintiffs' business reputation.

106. Because Plaintiffs' remedies at law are not adequate to compensate for all the injuries inflicted by Defendant, Plaintiffs are entitled to entry of preliminary and permanent

injunctive relief requiring Defendant to cease its false and misleading advertising and promotion and unfair competitive practices.

107. Because the above-described acts of Defendant are willful, Plaintiffs are entitled to disgorgement of Defendant's profits (enhanced at the Court's discretion), treble damages, and costs under 15 U.S.C. § 1117.

108. This case is exceptional, making Plaintiffs eligible for an award of attorneys' fees under 15 U.S.C. § 1117.

FOURTH CAUSE OF ACTION

Unfair Competition in Violation of the Common Law

109. Plaintiffs reallege and incorporate each allegation in the preceding paragraphs of this Complaint as though fully set forth here.

110. The above-described acts of Defendant constitute common law unfair competition.

111. The above-described acts of Defendant unfairly and wrongfully exploit Plaintiffs' trademark, goodwill, and reputation.

112. By reason of the above-described acts of Defendant, Plaintiffs have suffered damage to the goodwill associated with the Ozempic® and Wegovy® trademarks.

113. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs and the Ozempic® and Wegovy® trademarks.

114. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

115. Because Plaintiffs' remedies at law are not adequate to compensate for the injuries inflicted by Defendant, the Court should enter preliminary and injunctive relief in addition to awarding disgorgement of Defendant's profits (enhanced at the Court's discretion) and corrective advertising costs to NNAS.

FIFTH CAUSE OF ACTION

Deceptive Trade Practices in Violation of Ohio R.C. 4165.01 et seq.

116. Plaintiffs reallege and incorporate each allegation in the preceding paragraphs of this Complaint as though fully set forth here.

117. The above-described acts of Defendant constitute deceptive trade practices in violation of Ohio law.

118. Specifically, said acts are likely to cause confusion as to source, sponsorship, approval, or certification of goods or services in violation of R.C. 4165.02(A)(2) and are likely to mislead consumers as to the standard, quality, or grade of Defendant's products in violation of R.C. 4165.02(A)(9).

119. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

120. By reason of Defendant's willful acts, Plaintiffs' remedies at law are not adequate to compensate for the injuries inflicted by Defendant. Accordingly, the Court should enter preliminary and permanent injunctive relief, in addition to awarding damages and attorney's fees.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request judgment against Defendant as follows:

1. That the Court enter a judgment against Defendant that Defendant has:

   a. Infringed the rights of Plaintiff NNAS in its federally registered Ozempic® and Wegovy® marks in violation of 15 U.S.C. § 1114(1);

   b. Infringed the rights of Plaintiffs in the Ozempic® and Wegovy® marks and engaged in unfair competition, in violation of 15 U.S.C. § 1125(a);

   c. Engaged in false and misleading advertising and promotion, in violation of 15 U.S.C. § 1125(a);

d. Engaged in unfair competition under the common law of Ohio and Ohio's Deceptive Trade Practices laws.

2. That the Court find that each of the above acts was willful.

3. That the Court preliminarily and permanently enjoin and restrain Defendant and its agents, servants, employees, successors, and assigns, and all other persons acting in concert with or in conspiracy with or affiliated with Defendant, from:

a. using the Ozempic® and Wegovy® marks, including (i) use in any manner that is likely to cause confusion or mistake, to deceive, or otherwise infringe Novo Nordisk's rights in the Ozempic® and Wegovy® mark or (ii) use in connection with the advertising, marketing, sale, or promotion of any Unapproved Compounded Drugs; and,

b. advertising, stating, or suggesting that any Unapproved Compounded Drugs, including any Unapproved Compounded Drugs that either are available, directly or indirectly, from or through Defendant or the use of which or access to which is facilitated by, or with the involvement of, Defendant:

i. are, or contain, genuine or authentic Novo Nordisk Ozempic® or Wegovy® medicines;

ii. are sponsored by or associated with Novo Nordisk;

iii. are approved by the FDA; have been reviewed by the FDA for safety, effectiveness, or quality; or have been demonstrated to the FDA to be safe or effective for their intended use;

iv. achieve or have been shown or proven to achieve certain therapeutic results, effects, or outcomes, including by relying on or making reference to clinical trial results for Novo Nordisk's medicines;

v. achieve or have been shown or proven to achieve therapeutic results, effects, or outcomes similar or identical to Novo Nordisk's medicines or are interchangeable with or equivalent to genuine Novo Nordisk medicines;

vi. are associated or connected with Novo Nordisk or Novo Nordisk's medicines; or

vii. contain any ingredient (including but not limited to semaglutide) that is supplied by Novo Nordisk, is approved by the FDA, or is the same as any ingredient in any Novo Nordisk medicine.

c. engaging in any unfair competition with Plaintiffs; and

d. engaging in any deceptive acts or practices.

4. That the Court require Defendant to disclose conspicuously and prominently in any public-facing materials for any Unapproved Compounded Drugs, including all advertising, marketing, and promotional materials, that: (a) the Unapproved Compounded Drugs are compounded drugs that have not been approved by the FDA; have not been reviewed by the FDA for safety, effectiveness, or quality; and have not been demonstrated to the FDA to be safe or effective for their intended use; (b) the processes by which the compounded drugs are manufactured have not been reviewed by the FDA; and (c) FDA-approved medicines containing semaglutide are available.

5. That the Court award Plaintiffs monetary relief in the form of disgorgement of Defendant's profits for Defendant's trademark infringement, false advertising, and unfair competition and that this monetary relief be trebled due to Defendant's willfulness, in accordance with the provisions of 15 U.S.C. § 1117 and any applicable state laws.

6. That the Court award disgorgement of Defendant's profits resulting from Defendant's infringement of Plaintiffs' rights and by means of Defendant's unfair competition to Plaintiffs.

7. That the Court order Defendant to account for and disgorge to Plaintiffs all amounts by which Defendant has been unjustly enriched by reason of Defendant's unlawful actions.

8. That the Court award Plaintiffs punitive damages by reason of Defendant's willful unlawful actions.

9. That the Court award Plaintiffs pre-judgment and post-judgment interest on all damages.

10. That the Court award Plaintiffs their reasonable attorneys' fees pursuant to 15 U.S.C. § 1117 and any other applicable provision of law.

11. That the Court award Plaintiffs the costs of suit incurred herein.

12. That the Court award such other or further relief as the Court may deem just and proper.

October 11, 2024

Respectfully submitted,

By: */s/ Gregory J. Krabacher*

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